

**REMARKS**

Applicants acknowledge receipt of an Office Action dated May 7, 2003. In this response, Applicants have cancelled previously pending claims 11-20 and have added new claims 21-34 which have been drafted in more appropriate U.S. style format. Following entry of these amendments, claims 21-34 are pending in the application.

Reconsideration of the present application is respectfully requested in view of the foregoing amendments and the remarks which follow.

**Request for Clarification**

Applicants note that the PTO has only rejected claims 11-19 in the Office Action and nowhere addressed claim 20. Applicants respectfully request that the PTO consider and address all of the currently pending claims in the next Office Action.

**Rejections Under 35 U.S.C. §112, 2<sup>nd</sup> Paragraph and 35 U.S.C. §101**

On page 2 of the Office Action, the PTO has rejected claims 11-19 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph as allegedly being indefinite because the claims "[do] not set forth any steps involved in a method/process. On the same page, the PTO has also rejected claimed 11-19 under 35 U.S.C. §101 "because the claimed recitation of a use, without setting forth any steps involved in the process results in an improper definition of a process."

In this response, Applicants have cancelled claims 11-19, thereby rendering the outstanding rejections of these claims moot. In addition, Applicants have added claims 21-34 which have been drafted in more appropriate U.S. style format and which recite active method steps. In view of these amendments, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections under 35 U.S.C. §112, 2<sup>nd</sup> paragraph and under 35 U.S.C. §101.

**Rejections Under 35 U.S.C. §102 - Bang**

On page 2 of the Office Action, the PTO has rejected claims 11, 13, 16 and 19 under 35 U.S.C. §102(b) as being anticipated by WO 98/47502 to Bang *et al.* (hereafter "Bang").

As discussed above, Applicants have cancelled claims 11-19 and have replaced these claims with new claims 21-34. For the reasons set forth below, Applicants submit that the anticipation rejection based on Bang does not properly apply to newly added claim 21 or the claims which ultimately depend therefrom.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See generally MPEP §2131.

Here, Bang only discloses the use of R-ibuprofen-CoA-thioesters and the use of R-ibuprofen as a prodrug which is reacted in the body to form its CoA thioester as an active compound. Bang fails to disclose administration of "a composition comprising an R-enantiomer of an arylpropionic acid or a derivative thereof which does not metabolize to CoA thioesters selected from R-flurbiprofen, R-ketoprofen, R-naproxen, R-tiaprofenic acid, and/or R-fenoprofen to a human subject in need thereof" as recited in claim 21. The R-arylpropionic acids according to newly added claim 21 do not react in the human body to form the CoA-thioester intermediate comparable to the compounds of Bang and therefore are not inverted to form the respective S-enantiomers.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the outstanding anticipation rejection based on Bang.

#### **Rejections Under 35 U.S.C. §102 - Geisslinger**

On page 3 of the Office Action, the PTO has rejected claims 11-18 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,200,198 to Geisslinger *et al.* (hereafter "Geisslinger"). As discussed above, Applicants have cancelled claims 11-19 and have replaced these claims with new claims 21-34. For the reasons set forth below, Applicants submit that the anticipation rejection based on Geisslinger does not properly apply to newly added claim 21 or the claims which ultimately depend therefrom.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See generally MPEP §2131. Here, Geisslinger fails to disclose a "method for treatment of diseases influenced by the inhibition of NF- $\kappa$ B production" as recited in independent claim 21. Geisslinger discloses a short term pain killing action of R-flurbiprofen, which is assumed to react in the central nervous system (cns) (col. 2, lines 46-50) and produce neurophysiological effects as the result of the incorporation of the active materials in the cell membranes (col. 2, lines 61-63). This is in line with the disclosed experiment in column 6, which discloses an action inside 30 minutes after administration (col. 6, lines 33-39) and low to moderate dosages of 10-100 mg.

In contrast to the Geisslinger reference, the presently claimed method relates to the treatment of diseases induced by the action of NF- $\kappa$ B, i.e. long lasting rheumatic diseases, asthma, tumors, etc., which are combated by a long lasting depletion of the production of NF- $\kappa$ B by comparatively larger dosages per day, which are applied over periods ranging from a month to a number of years, i.e. as long as the basic chronic disease lasts. This influences the corresponding inflammation processes in the peripheric bone joints, muscles, etc. and only by secondary action relieves the pain associated therewith.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the outstanding anticipation rejection based on Geisslinger.

### **Rejections Under 35 U.S.C. §103**

On page 3 of the Office Action, the PTO has rejected claims 11-19 under 35 U.S.C. §103(a) as being unpatentable over Geisslinger. Applicants respectfully traverse this rejection for the reasons set forth below. As discussed above, Applicants have cancelled claims 11-19 and have introduced new claims 21-34.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). See MPEP §2143.03. As discussed above, Geisslinger fails to disclose a "method for treatment of

diseases influenced by the inhibition of NF- $\kappa$ B production" as recited in independent claim 21. Geisslinger discloses a short term pain killing action of R-flurbiprofen, which is assumed to react in the central nervous system (cns) (col. 2, lines 46-50) and produce neurophysiological effects as the result of the incorporation of the active materials in the cell membranes (col. 2, lines 61-63). This is in line with the disclosed experiment in column 6, which discloses an action inside 30 minutes after administration (col. 6, lines 33-39) and low to moderate dosages of 10-100 mg.

In contrast to the Geisslinger reference, the presently claimed method relates to the treatment of diseases induced by the action of NF- $\kappa$ B, i.e. long lasting rheumatic diseases, asthma, tumors, etc., which are combated by a long lasting depletion of the production of NF- $\kappa$ B by comparatively larger dosages per day, which are applied over periods ranging from a month to a number of years, i.e. as long as the basic chronic disease lasts. This influences the corresponding inflammation processes in the peripheric bone joints, muscles, etc. and only by secondary action relieves the pain associated therewith.

If an independent claim is nonobvious under §103, then any claim depending therefrom is nonobvious. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). See MPEP 2143.03. Thus, Applicants submit that claims 22-34, which ultimately depend from independent claim 21, are also non-obvious.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the outstanding §103 rejection based on Geisslinger.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment,

to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By R.D.S.

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